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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,647	03/10/2000	Andrew D. Murdin	032931/0227	5021

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EXAMINER	
NAVARRO, ALBERT MARK	

ART UNIT	PAPER NUMBER
1645	16

DATE MAILED: 01/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/523,647	Murdin et al
Examiner	**Art Unit**
Mark Navarro	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 18, 2002*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *8, 9, 11, and 38* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *8, 9, 11, and 38* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Vacated 1/6/03

DETAILED ACTION

Continued Prosecution Application

1. The request filed on December 18, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/523,647 is acceptable and a CPA has been established. An action on the CPA follows.

Applicant's amendment filed on December 18, 2002 (Paper Number 15) has been received and entered. Claims 1-7, 10, and 12-37 have been canceled, consequently claims 8-9, 11 and 38 are pending in the instant application.

Claim Rejections - 35 USC § 112

2. The rejection of claims 8-9, 11, and 38 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition comprising a vector which encodes SEQ ID NO: 2, does not reasonably provide enablement for a pharmaceutical composition or a vaccine comprising SEQ ID NO: 2 or any immunogenic fragment comprising at least 12 consecutive amino acids or a polypeptide having 75% identity to SEQ ID NO: 2 is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification provides insufficient guidance of how to use the claimed vaccine to induce a protective immune response. It is well recognized in the art that it is unclear whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A et al.,(ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies ...and thus protect the host against attack by the pathogen." Since no working examples are set forth in the specification that the claimed nucleotide molecules encode a polypeptide which elicits protective immunity and the art teaches of the unpredictability of using a single antigen for vaccination it would be an undue burden and be unpredictable to use the broadly claimed product for inducing a protective immune response.

It is noted that example three of the specification describes the immunization of mice to achieve protection against an intranasal challenge of C. pneumoniae. However, Applicant's have defined protective immunity "as an accelerated clearance of pulmonary infection." (Page 56, lines 3-4). Applicant's further challenged with a "sublethal" C. pneumoniae lung infection. Applicant's results clearly show an immune response elicited, however challenging with sublethal amounts of C. pneumoniae does not establish a determination of protection. A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

3. The rejection of claims 8-9, 11 and 38 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 8-9, 11 and 38 recite a nucleic acid molecule encoding a polypeptide comprising at least 12 consecutive amino acids of SEQ ID NO: 2 or a polypeptide having 75% identity to the amino acid sequence of SEQ ID NO: 2 .

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 1 which encodes SEQ ID NO: 2 alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by the 12 consecutive amino acids of SEQ ID NO: 2 or a function of polypeptides having 75% identity to SEQ ID NO: 2 which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See

Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 8-9, 11 and 38 under 35 U.S.C. 102(b) as being anticipated by Watson et al is maintained.

The claims are directed to a vaccine comprising a vaccine vector and at least one first nucleic acid molecule, and wherein the nucleic acid molecule comprises a nucleic acid molecule comprising a nucleic acid sequence which encodes a polypeptide selected from any one of: SEQ ID NO: 2, an immunogenic fragment comprising at least 12 consecutive amino acids from a polypeptide of SEQ ID NO: 2, and polypeptides having 75% identity to SEQ ID NO: 2.

Watson et al (Microbiology Vol. 141(Pt 10) pp 2489-2497, 1995) disclose of generating vectors comprising inserting the DNA sequence encoding the 60 kDa and 9 kDa cysteine rich proteins of C. pneumoniae. (See abstract and page 2490). Watson et al further disclose of the nucleotide sequence of the DNA molecule encoding the 60 kDa cysteine rich protein to encode a protein with 100% identity with SEQ ID NO: 2 of the instant invention. Watson et al further disclose of the vector including the 9 kDa protein, as well as diluents suitable for use in a vaccine.

In view that Watson et al disclose of a vector comprising an insert encoding a protein having the identical sequence as SEQ ID NO: 2 of the instant invention, the disclosure of Watson et al is deemed to anticipate the claimed invention.

It is noted that Watson et al do not refer to the vector as a "vaccine." However, the recitation of vaccine is merely an intended use of the claimed vector, and carries no patentable weight when compared to the product, (i.e., vector).

5. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.53(d). Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first

action after the submission under 37 CFR 1.53(d). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

January 9, 2002